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# ENVIRONMENTAL DEFENSE FUND

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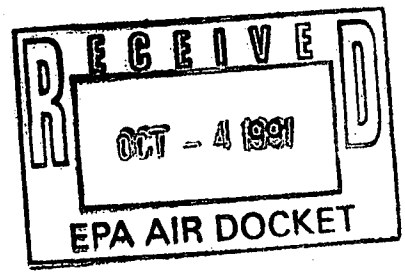


RE: Docket A-91-46

Dear Sir or Madam:

Enclosed please find an original and two copies of the EDF's comments on the above-captioned rulemaking.

Thank you for your assistance.

Very truly yours,

Karen Florini
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cc (by mail):

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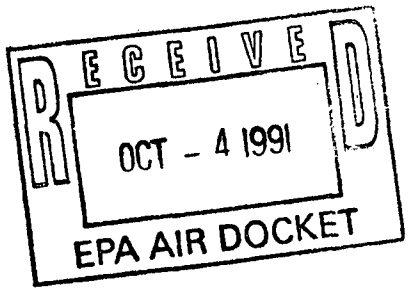


## COMMENTS OF THE ENVIRONMENTAL DEFENSE FUND

## ON THE ETHYL CORPORATION'S APPLICATION FOR A WAIVER UNDER SECTION 211 OF THE CLEAN AIR ACT ALLOWING USE OF METHYLCYCLOPENTADIENYL MANGANESE TRICARBONYL (MMT) AS A GASOLINE ADDITIVE (56 Fed. Reg. 36810 (August 1, 1991))

Docket No. 91-17988

Submitted October 4, 1991

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The Environmental Defense Fund (EDF) submits these comments on the application by the Ethyl Corporation to add methylcyclopentadienyl manganese tricarbonyl (MMT), an organo-manganese compound, to gasoline as an octane enhancer. See 56 Fed. Reg. 36810 (August 1, 1991) (notice of waiver application).

EDF is a national, nonprofit, environmental research and advocacy organization with over 200,000 members throughout the United States. In the 24 years since its founding in 1967, EDF has worked extensively on environmental problems of heavy metal contamination from gasoline and other sources, as well as a variety of other toxic exposures. EDF staff have extensive experience relating to manganese and other environmental neurotoxins, including serving as a peer reviewer of EPA's most recent health assessment of manganese, and of the recent Health Effects Institute paper on the health effects of manganese as an additive to gasoline. EDF staff have also served on several EPA committees charged with assessing environmental fate and transport, exposure, and health impacts of another organo-metal gasoline additive, tetraethyl lead.

Introduction and Summary

EDF strongly opposes granting this waiver application. The Clean Air Act provides that EPA "may" grant a waiver allowing the use of manganese as a fuel additive upon determining that it will not contribute to the failure of emissions control devices, such as catalytic converters, which are designed to bring vehicles into compliance with the emmisions standards of the Clean Air Act. 42 U.S.C. Section 7545(f)(4). By using the term "may," the Act expressly indicates that the Administrator has discretion to deny a waiver application even if he concludes that the additive will not cause such impairment. Regardless of the effects of MMT on emissions control devices, there is no dispute that manganese is neurotoxic to humans as discussed at length in Part II of the comments. On this basis, the Administrator should exercise his discretion to deny this waiver application, particularly since Ethyl has failed to provide relevant or convincing evidence that use of MMT will not affect human health. EDF believes that failure to deny this application would be arbitrary, capricious, and an abrogation of EPA's clear responsibility under the Clean Air Act to protect human health. These comments incorporate by reference the Statement of EDF Senior Toxicologist Ellen K. Silbergeld submitted in conjunction with the June 22, 1990, hearing on Ethyl's prior application for use of MMT (EPA Docket No. A-90-16).

## I. Statutory Framework

### A. The Clean Air Act's Fundamental Objective of Protecting Human Health and the Environment Mandates Denial of the Waiver Application

Section 211(f)(4) states "The Administrator . . . may waive the prohibitions established under paragraph (1) or (3) of this subsection" upon determining that the proposed additive will not impair the efficiency of an emission control device (emphasis supplied). By using the discretionary term "may," the statute empowers the Administrator to grant a waiver if a no-impairment demonstration is made. In exercising the discretion thus bestowed, however, the Administrator must consider the basic purposes of the Act as a whole, and other relevant statutes and policies.[1]

Section 101 of the Clean Air Act expressly states that

> The purposes of this subchapter are --
>
> (1) to protect and enhance the quality of the Nation's air resources so as to promote the public health and welfare and the productive capacity of its population;
> . . . .

Section 101(b), 42 U.S.C. section 7401(b).

In crafting the 1977 Amendments to the Act, the House stressed the significance of this protective mandate in the implementation of the Act. In particular, the House Committee strongly endorsed the D.C. Circuit's conclusion -- articulated in a case brought by petitioner Ethyl Corporation challenging EPA restrictions on the use of lead as a gasoline additive -- that EPA was authorized to take a preventive, protective approach in the face of scientific uncertainty. The Committee indicated that this preventive approach was applicable to the act as a whole. H.R. Rep. No. 294, 95th Cong. 1st Sess. 49,

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[1] Significantly, information submitted to EPA's docket regarding Ethyl's prior petition strongly suggests that no non-impairment finding can be made in any event. Numerous parties concerned with this waiver request have presented compelling evidence that MMT will have serious detrimental effects on emissions control devices. For example, the Manufacturers of Emissions Controls Association indicates that manganese oxide produced by MMT: 1) completely clogs small flow channels of monolith catalysts, 2) forms a coating that decreases catalyst performance, 3) causes specific chemical reactions resulting in the collapse of the catalyst surface, and 4) causes other negative effects on the performance of emissions control devices. (July 19, 1990 letter from Manufacturers of Emissions Controls Association, submitted in conjunction with the 1990 MMT application). As a result of these data and similar data submitted by other commenters in conjunction with the 1991 MMT application, the waiver request must be denied even independent of its health effects.

*reprinted in* 1977 U.S.Code Cong. & Ad. News 1077, 1127 (emphasizing "the preventive or precautionary nature of the act, i.e., to assure that regulatory action can effectively prevent harm before it occurs" and "the predominant value of protection of public health") (emphasis added). These authorities were fully incorporated in the fuel-additives provisions: "Section 211 conferred the broad authority necessary to protect the public health and to assure the efficacy of emission control devices and systems." Id. at 294, 1977 U.S.Code Cong. & Ad. News at 1385 (emphasis added).

Ironically, during the 1977 reauthorization process, then-existing uses of MMT were a source of considerable controversy focusing on MMT's effects on emission-control devices. But the Committee's logic is equally applicable to biomedical concerns: "[t]he MMT problem shows the fallacy of waiting until an additive is already in widespread use and a problem has already developed; the preventive approach, as emphasized in the previous discussions of [other provisions] is essential for the purpose of this section [i.e., section 211] as well." Id. at 308, 1977 U.S.Code Cong. & Ad. News at 1387. The Committee further noted "the paramount interest in protection of public health" in the context of fuel additives. Id. at 308, 1977 U.S. Code Cong. & Ad. News at 1388.

Moreover, the structure of the statute makes clear that EPA is not obliged to undertake extensive fact-finding before denying a waiver application, as is illustrated by the contrast between sections 211(c) and 211(f). While the former expressly requires EPA to consider a variety of factors before banning an existing fuel or fuel additive, the latter requires no such analyses as a precondition of disapproving the introduction of a new fuel or additive. The disparity between the two sections reveals that Congress knew full well how to require such analyses when it so desired, and indicates that EPA plainly need not conduct analogous assessments before denying a waiver application under section 211(f). Indeed, in light of the fundamental objective of the Clean Air Act -- protection of public health -- the Administrator can properly exercise his discretion to grant a waiver only upon determining that doing so will not impair public health.

B. Additional Policy and Statutory Bases Independently Warrant Denial of the Waiver Application

In addition to the obligations imposed on EPA under the Clean Air Act, Section 101(b) of the National Environmental Policy Act calls on the Federal Government "to use all practicable means and measures" to carry out the Congressional purpose declared in Section 2: "to promote efforts which will prevent or eliminate damage to the environment." See 42 U.S.C. S. 4321, 4331(b). This obligation to promote and protect the environment binds the EPA no less than any other federal agency; in light of the scientific data on manganese itself and experience with other heavy metals in similar products, failure to deny Ethyl's waiver application would plainly violate NEPA's mandate.

Finally, granting the waiver application -- and thus allowing an inherently dispersive use of a known neurotoxin -- would be inconsistent with EPA's recently announced policy of pollution prevention. Indeed, allowing such a use of a neurotoxic compound can only be characterized as pollution *promotion*. Use of MMT as a gasoline additive will not only contaminate ambient air and soils (and, eventually, other media as well), but also automobiles, thus impeding the recycling of cars when they are scrapped at the end of their useful life. In a recent policy statement, the Agency proclaimed its view that "pollution prevention through source reduction and environmentally sound recycling is highly desirable," and described the development of a multi-media pollution prevention program "to ensure that the pollution prevention philosophy is incorporated into every feasible aspect of internal EPA decisionmaking and planning." Pollution Prevention Policy Statement, 54 Fed. Reg. 3845 (January 26, 1989) (proposed statement). It is impossible to reconcile this important policy with allowing the introduction and widespread use of a neurotoxic fuel additive.

In sum, denying the waiver application would plainly comport with the congressional and EPA policy of preventing air pollution before it does damage to human health or the environment. Moreover, as further discussed below, in light of our society's prior painful experience with neurotoxic fuel additives, and the existing state of knowledge regarding manganese, denial of the waiver application is the only rational decision.

## II. Environmental and Human Health Issues

It is rare that an opportunity arises to base public policy on the clear lessons of a real-life, multi-decade experiment involving closely similar matters. Failure to heed those lessons invites repetition of the public health catastrophe associated with the use of lead as a gasoline additive from 1925 to 1975 (and, to a lesser degree, to the present). The 1988 ATSDR report to Congress on childhood lead poisoning documents that lead toxicity is epidemic in the United States. Even after considerable reductions have been imposed on the use of lead in gasoline, we are only now confronting the extraordinarily difficult challenge of cleaning up the residues of lead fallout from city playgrounds, school yards, and backyards around America.[2]

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[2] Dr. Katherine Farrell and Dr. Boon Lim, of the Maryland Department of Environment, are currently conducting research, sponsored by EPA, on the significance of soil lead as a source of exposure for urban children; a recent report from the California Department of Health Services already demonstrates the quantitative relationship between soil lead and children's blood lead levels. See State of California Department of Health Services, *Childhood Lead Poisoning in California: Causes and Prevention* (June 1989).

This is an experience we cannot afford to repeat. The parallels between the 1991 proposal to use manganese and the 1925 proposal to use lead, are chilling. In both cases, the exclusive basis for the application is the additive's purported effect on automobiles. No data were or are submitted on the potential cumulative health effects of massive inputs of a toxic metal into the environment, its deposition into surface dusts and soils, and its longterm fate and exposure pathways to humans. In 1925, it was argued that the amounts of lead to be added to gasoline were of negligible importance, and that lead was only toxic at the high doses encountered in certain industrial settings. In 1991, it is argued that the releases of manganese to the environment will be insignificant and that manganese is only toxic at high doses in industrial settings. Despite this lesson from the past, Ethyl's waiver application fails to document either the environmental fate of manganese from MMT use, or the human health consequences of exposure to manganese arising from such use.

-- Inadequacies in the Waiver Application Regarding Environmental Fate

Wholly inadequate data are presented to indicate that adding manganese to gasoline does not change concentrations of manganese in ambient air over the short term in some selected Canadian cities. Conspicuous by its absence is any citation or discussion of a recent study from California indicating that increases in airborne manganese in air samples are related to additions of manganese to gasoline already permitted by EPA (see Davis, et al, 1988; references attached to Silbergeld testimony submitted at public hearing June 22, 1990 (hereinafter "Silbergeld testimony")). No in-depth discussion of the health effects of manganese is presented, nor -- more importantly -- is there a discussion of the critical data gaps on manganese toxicity that must be filled before any decision can be approved that would result in tons of manganese being released into the environment (see bibliography attached to Silbergeld testimony).

Ethyl has chosen to focus in its application on the purported efficacy of manganese additives to reduce certain pollutant emissions from vehicles. In a well-mounted publicity campaign over the past weeks, Ethyl has sought to harness concerns over the impacts of these air pollutants on global and local air quality as justification. Ethyl has selectively cited bits of data in support of its contention that use of MMT will not increase manganese concentrations in air in cities. But Ethyl has provided failed to provide adequate data on impacts of manganese additives on manganese concentrations in more stable post-deposition compartments, such as dusts and soils.

These deficiencies preclude granting of this waiver application. Indeed, the requested waiver cannot be approved until the applicant provides substantive information on the cumulative impacts of manganese additives on environmental quality (not solely ambient air concentrations) and convincing evidence that such impacts will not adversely affect the health of any segment of the human population over the long term.

In making this case, Ethyl must demonstrate that the likely experience with manganese will not resemble that with lead. This demonstration will be difficult. Both lead and manganese are elements and as such will not degrade or quickly disappear from stable environmental compartments, such as soils, dusts, and sediments. Patterns of use will result in relative enrichment in urban, densely populated areas with high levels of vehicular traffic and will inevitably result in greatly increased human exposure. While the proposed per-gallon usage of manganese is less than the usage of lead in gasoline at its peak prior to regulation in 1978, the vastly increased amount of gasoline consumed and number of vehicle miles driven in the U.S. in 1990 as compared to 1925 will ensure that the rate of contamination of our environment from this source will be comparable.

-- Inadequacies in the Waiver Application Regarding Neurotoxicity

Both lead and manganese are neurotoxic metals. While the data on manganese is relatively sparse (compared to lead -- but we have not yet conducted a massive human experiment with manganese), the hazard identification of manganese as a neurotoxin and lung toxin is clear (see generally EPA's HAD on manganese and bibliography attached to Silbergeld testimony). Manganese, like lead, is a cumulative toxin in that both its absorption and retention as well as its toxicity increase with time. At present, there are insufficient data on the low-level chronic sequelae of manganese exposure, as was the case for lead in 1925. There are no data on the effects of manganese on the ageing brain, although it has been suggested that the nature of manganese-induced pathophysiology -- damage to the nigrostriatal system -- is such that interaction with normal cell loss during senescence would be expected. The potential for selective susceptibility to manganese in the aged must be of great concern as the U.S. population ages. Studies on the population of Groote Eylandt disease by Cawte suggest that there may also be fetal and early developmental effects of manganese. The possibility that iron deficiency may potentiate manganese toxicity is of considerable concern, given the prevalence of iron deficiency in the U.S. as indicated by NHANES II.

The mechanisms by which manganese damages neural tissue (particularly catecholaminergic pathways) are unknown, so that we cannot propose an overall dose response relationship or rational basis for risk assessment. There are inadequate studies on the immunotoxic effects of MMT or manganese. The toxicokinetics of low dose manganese exposure are not known; the observations of apparent decreases in brain manganese concentrations with prolonged exposure are at relatively high exposures and may reflect a pathological effect (e.g., loss of normal manganese binding sites, such as enzymes or other proteins) rather than a protective effect. These rather odd toxicokinetics have not been replicated in primates. Moreover, as the study by Yamada et al. indicates, the expression of severe akinetic and neuropsychiatric symptoms were not associated with increased concentrations of manganese in brain, further

indicating that the mechanisms as well as the toxicokinetics of manganese are not well understood. No defined biological markers for manganese exposure in humans have been validated, so that interpretation of epidemiological studies is limited.

These concerns were further highlighted during the March 1991 NIEHS conference on manganese. That conference identified numerous critical research gaps that would have to be filled before use of MMT could be approved. The Summary Report of that Workshop is hereby incorporated by reference into these comments.

Conclusion

In summary, both what we know and do not know at present about the likely toxic effects of adding manganese in large total amounts to the environment must persuade EPA to reject this application. We know that manganese at high dose is a demonstrated human neurotoxin, with persistent and irreversible pathological effects on brain structure and resulting severe impairments in movement and mental state. We do not know what the longterm, chronic, low dose consequences of human exposure to manganese are. We do not know a "safe" level of manganese exposure, particularly for those subgroups that may be at increased risk for neurotoxicity (the young and the aged). We do not know if manganese is carcinogenic, although there is evidence that it can break DNA.

In contrast, based upon our tragic experience with lead, we know a great deal with respect to exposure assessment about the likely cumulative impacts of such a use upon human exposure to manganese. We know that the gradual contamination of the environment by this additive will not be readily reversed, and that manganese will accumulate in specific parts of the environment, many of which are subject to intensive human interaction (urban dusts and soils). We know that manganese in air and in surface dusts and soils will be present directly to humans as a source of exposure.

Granting the waiver of Ethyl's application for the use of MMT in the face of substantial amounts of unquantified risk and demonstrated potential for harm would be at best a reckless experiment on the effects of manganese upon human health and the environment, and at worst an invitation to disaster. Forcing future generations to bear the brunt of this risk and the costs of rectifying the damage done is unpardonable. Denying this application is the only choice that comports with Congressional intent, scientific prudence, and a rational public policy of human health and environmental protection.

Respectfully submitted,

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